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PATENT DEPARTMENT
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EXAMINER	
CRAIGO, WILLIAM A	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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DETAILED ACTION

Response to Arguments

Applicant's arguments filed 15 September, 2011 have been fully considered but they are not persuasive.

Applicant argues the skilled artisan at the time the invention was made would not have considered delivering peptides, polypeptides or proteins in a patch because the teachings of Avrahami are limited to commercially available skin patches and transdermal delivery through intact skin from a patch of peptides, polypeptides or proteins was known to the skilled artisan to be negligible.

This is not persuasive because; first, the claimed method and the primary reference Avrahami both state microchannels are formed in the skin; accordingly the skin is not "intact" in the sense of unaltered normal skin. While there may be no visible damage or blood, the skin still contains microchannels which are not present in unaltered intact skin. Second, the skilled artisan would certainly have been motivated in view of Avrahami teaching the application of a patch to look to the art for known patch vehicles for drugs. Avrahami expressly teaches "preferably, micro-channels allow the diffusion therethrough of large molecules at a greater rate than the **same molecules** would **diffuse** through pores generated by electroporation," (Avrahami, col. 3, lines 7-10, cited previously). Avrahami points the skilled artisan directly to art directed to transport of large molecules transdermally. As evidenced by the secondary references, patches for delivery of peptides, polypetides and proteins were known vehicles for the

delivery of peptides, polypeptides and proteins as claimed using matrices of hydrophilic polymers at the time the invention was made.

Applicant argues none of the secondary references cited remedy the deficiencies of Avrahami.

This is not persuasive in view of the discussion above.

Applicant argues Venkatraman, Phipps and Haak, disclose electrotransport drug delivery device which require application of electrical energy to the drug composition so as to iontophoretically deliver the drug into the subject's body.

This is not persuasive because the device of Avrahami creates micro-pores which are more efficient than the electrotransport drug delivery devices; Avrahami points directly to such art; the skilled artisan would have certainly been motivated to select known delivery vehicles for known therapeutic agents.

Applicant argues the teachings of Song do not relate to transdermal drug delivery (pg. 7); Song is limited to drug delivery to wound, burn or trauma sites only (pg.e 8).

This is not persuasive because Song is cited for teaching a layered drug delivery vehicle for delivery of peptides, polypeptide and proteins comprising layers of known hydrophilic vehicles; "collagen films of the present invention are useful as a means of delivering the active ingredients to cells or tissue with which it is in contact," (Song, col. 6, lines 19-21). Song is not limited to burns or trauma to the skin. Avrahami teaches transdermal delivery of drugs. It is noted that Avrahami and the present method both require trauma to the skin via the formation of micro-channels. Accordingly Song is relevant.

Applicant argues Farinas does not teach a peptide; further Farinas teaches heating the delivery vehicle to temperatures which would denature a protein and destry its activity.

This is not persuasive because Farinas was cited to show hydrophilic polymers known as vehicles for drugs for transdermal delivery. Further the claims are not limited to proteins. Simple peptides encompassed by the claims would not be denatured. Accordingly Farinas is relevant.

Applicant argues the type of patch is critical and very relevant to the method recited in claim 34 because the combination of generating micro-channels in the skin of a subject and affixing the specific patch which comprises a drug reservoir layer which is a matrix of a hydrophilic polymer and a pharmaceutical composition comprising a peptide, polypeptide or protein enables achieving sustained transdermal delivery of the peptide, polypeptide or protein.

This is not persuasive because the patch recited in claim 34 cannot reasonably be considered specific. There are many hydrophilic polymer matrices as evidenced by the cited references. Moreover, all the claimed hydrophilic polymeric matrices were known as transdermal drug delivery vehicles.

Applicant argues Farinas discloses hydrophobic polymers or alternatively a combination of hydrophobic and hydrophilic polymer for the drug reservoir, Farinas does not disclose or suggest a drug reservoir of a hydrophilic polymer.

This is not persuasive because at least Venkatraman clearly discloses hydrophilic polymers as preferred materials as a drug reservoir matrix due to their high

equilibrium water content, their ability to absorb water from the body, good biocompatibility with the skin and can be mixed in a dry (anhydrous) state for drug stability (Venkatraman, col. 3, lines 33-51). Farinas was cited for teaching art recognized hydrophilic polymers such as gelatin and carrageenan as preferred polymers for transdermal drug delivery (Farinas, col. 7, lines 10-15 and col. 8, lines 15-22). Accordingly Farinas is relevant.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the present case, Applicant's arguments on pg. 9 of the response are all directed to differences present in individual secondary references Farinas, Song.

Applicant again argues the skilled artisan would not have combined Avrahami and Venkatraman to arrive at the claimed invention because Venkatraman discloses electrotransport.

This is not persuasive because Avrahami discloses a device for creating micro-channels in skin as claimed allows diffusion of large molecules and is more efficient than electrotransport. The skilled artisan would have looked to the teachings of Venkatraman at least for the teachings of the drug reservoir because they are known to be effective for transporting large molecules such as peptides, polypeptides and proteins.

Conclusion

The rejections of record are maintained. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CRAIGO whose telephone number is (571)270-1347. The examiner can normally be reached on Monday - Friday, 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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